

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/SE 2003/001760

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 13-14  
because they relate to subject matter not required to be searched by this Authority, namely:  
see extra sheet
2. ☒ Claims Nos.: 1-12, partly  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
see extra sheet
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

1.

Claims 13-14 relate to methods of treatment of the human or animal body by surgery or by therapy/ diagnostic methods practised on the human or animal body/Rule 39.1.(iv). Nevertheless, a search has been executed for these claims. The search has been based on the alleged effects of the compounds/compositions.

2.

Present claims 1-12 relate to an extremely large number of possible processes/formulations. Support within the meaning of Article 6 PCT and / or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the processes/formulations claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible.

The expression "addition /.../ in a stepwise manner" is not explained in a satisfactory way; it is not evident whether the different substances that are added separately, or whether a mixture of substances is added a little at a time. The expression "minimize loss /.../ through adhesion" is not further unfolded. Therefore, the claims also lack clarity (Article 5 and 6 PCT). An attempt is made to define the process/formulation by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible

Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, that is the process according to claim 6, with the following assumptions:

1. The process/formulation relates to a composition for inhalation of a combination of at least two active components, preferably formoterol fumarate dihydrate and budesonide, where the composition is a suspension that is to be administered in a pMDI.
2. One active component is added before the other.
3. The process implies that adhesion to the equipment of the active component added last is minimized.

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## A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61K 31/575, A61K 31/167, A61K 9/72, A61J 3/00, A61P 11/06  
According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61K, A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI DATA, EPO-INTERNAL, PAJ, CADATA, EMBASE, MEDLINE, BIOSIS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6004537 A (FRANK E. BLONDINO ET AL), 21 December 1999 (21.12.1999), column 1, line 38 - line 46; column 4, line 35 - line 47, tables 1-2 --	1-14
X	WO 0178737 A1 (GLAXO GROUP LIMITED), 25 October 2001 (25.10.2001), examples 1-2 --	1-14
X	US 5972919 A (CHRISTER CARL GUSTAV CARLING ET AL), 26 October 1999 (26.10.1999), column 4, line 1 - line 22, example 2 --	1-14

☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

5 February 2004

Date of mailing of the international search report

10 -02- 2004

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## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9311773 A1 (AKTIEBOLAGET ASTRA), 24 June 1993 (24.06.1993), page 7, line 6 - line 28, example 2  --	1-14
X	WO 0053188 A1 (ASTRAZENECA AB), 14 Sept 2000 (14.09.2000), page 6, line 15 - line 22, examples 7-9  --	1-14
X	WO 0203958 A1 (ASTRAZENECA AB), 17 January 2002 (17.01.2002), examples  -- -----	1-14

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

24/12/2003

International application No.  
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US	6004537	A	21/12/1999	AU	2194900	A	03/07/2000
				BR	9916829	A	23/10/2001
				CA	2355932	A	22/06/2000
				CZ	20012216	A	17/04/2002
				EP	1140059	A	10/10/2001
				HU	0200014	A	29/06/2002
				JP	2002532418	T	02/10/2002
				PL	348809	A	17/06/2002
				WO	0035441	A	22/06/2000
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WO	0178737	A1	25/10/2001	AU	4671601	A	30/10/2001
				EP	1274435	A	15/01/2003
				GB	0009584	D	00/00/0000
				US	2003109510	A	12/06/2003
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US	5972919	A	26/10/1999	AT	213946	T	15/03/2002
				AU	673660	B	21/11/1996
				AU	3085892	A	19/07/1993
				CA	2123909	A,C	24/06/1993
				CA	2356145	A	24/06/1993
				CZ	291455	B	12/03/2003
				CZ	9401434	A	15/12/1994
				DE	10299033	I	00/00/0000
				DE	69232462	D,T	10/10/2002
				DK	613371	T	13/05/2002
				EP	0613371	A,B	07/09/1994
				SE	0613371	T3	
				EP	1086697	A	28/03/2001
				EP	1101493	A	23/05/2001
				ES	2172510	T	01/10/2002
				HK	1010339	A	00/00/0000
				HR	921445	A	31/12/1994
				HU	75156	A	28/04/1997
				HU	0004452	D	00/00/0000
				HU	9401843	D	00/00/0000
				JP	3342484	B	11/11/2002
				JP	7502036	T	02/03/1995
				LU	90941	A	30/09/2002
				NO	306452	B	08/11/1999
				NO	942116	A	07/06/1994
				NZ	246050	A	21/12/1995
				PT	613371	T	31/07/2002
				SG	48301	A	17/04/1998
				SI	9200403	A,B	30/06/1993
				SK	73394	A	08/03/1995
				SK	282826	B	03/12/2002
				US	5674860	A	07/10/1997
				WO	9311773	A	24/06/1993

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WO	9311773	A1	24/06/1993	AT	213946	T	15/03/2002
				AU	673660	B	21/11/1996
				AU	3085892	A	19/07/1993
				CA	2123909	A,C	24/06/1993
				CA	2356145	A	24/06/1993
				CZ	291455	B	12/03/2003
				CZ	9401434	A	15/12/1994
				DE	10299033	I	00/00/0000
				DE	69232462	D,T	10/10/2002
				DK	613371	T	13/05/2002
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				SE	0613371	T3	
				EP	1086697	A	28/03/2001
				EP	1101493	A	23/05/2001
				ES	2172510	T	01/10/2002
				HK	1010339	A	00/00/0000
				HR	921445	A	31/12/1994
				HU	75156	A	28/04/1997
				HU	0004452	D	00/00/0000
				HU	9401843	D	00/00/0000
				JP	3342484	B	11/11/2002
				JP	7502036	T	02/03/1995
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				NO	306452	B	08/11/1999
				NO	942116	A	07/06/1994
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				PT	613371	T	31/07/2002
				SG	48301	A	17/04/1998
				SI	9200403	A,B	30/06/1993
				SK	73394	A	08/03/1995
				SK	282826	B	03/12/2002
				US	5674860	A	07/10/1997
				US	5972919	A	26/10/1999
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WO	0053188	A1	14/09/2000	AU	752978	B	03/10/2002
				AU	3687500	A	28/09/2000
				AU	4405399	A	06/12/1999
				CA	2333255	A	25/11/1999
				EP	1077632	A	28/02/2001
				JP	2002515274	T	28/05/2002
				SE	9900834	D	00/00/0000
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WO	0203958	A1	17/01/2002	AU	7286601	A	21/01/2002
				BR	0112322	A	08/07/2003
				CA	2415092	A	17/01/2002
				CN	1455663	T	12/11/2003
				EP	1303258	A	23/04/2003
				GB	0016876	D	00/00/0000
				NO	20030133	A	24/02/2003
				US	2003194378	A	16/10/2003